

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

DEBRA HATFIELD, EXECUTRIX OF THE
ESTATE OF BRIAN GRAVELY

Plaintiff,

v.

MDL NO. 2804
CASE NO. 1:19-op-45805

JURY TRIAL DEMANDED

MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,
DEPOMED, INC.;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
SPECGX LLC;
PAR PHARMACEUTICAL, INC.;
PAR PHARMACEUTICAL COMPANIES, INC.;
NORAMCO, INC.;
INDIVIOR, INC.;
CVS HEALTH CORPORATION;
RITE AID OF MARYLAND, INC.;
RITE AID CORP.;
WALGREENS BOOTS ALLIANCE, INC.;
WALGREEN EASTERN CO.;
WALGREEN CO.;
WAL-MART INC. f/k/a WALMART STORES, INC.;
MIAMI-LUKEN, INC.;

**COSTCO WHOLESALE CORPORATION;
THE KROGER CO.;
H.D. SMITH, LLC;
H.D. SMITH HOLDINGS, LLC;
H.D. SMITH HOLDING COMPANY;
ANDA, INC.;**

Defendants.

COMPLAINT

NOW COMES Plaintiff DEBRA HATFIELD [“Plaintiff”], as Executrix of the Estate of BRIAN GRAVELY, hereby filing their Complaint against the Defendants for damages, equitable, statutory, and injunctive relief. In support thereof, Plaintiff states as follows:

INTRODUCTION

1. Prescription opioids have devastated communities across the country and in the State of WEST VIRGINIA. Since 1999, there have been more than 351,000 reported opioid-related deaths nationwide—more than six times the number of U.S. soldiers who died in the Vietnam War. In addition to the tragic loss of life and the heartbreaking impact on children and loved ones, some estimates state that the opioid crisis is costing governmental entities and private companies as much as \$500 billion per year.

2. Defendants manufacture, market, sell, and distribute prescription opioids, which are powerful, highly addictive narcotic painkillers. The Manufacturer Defendants have engaged in a cunning and deceptive marketing scheme to encourage doctors and patients to use opioids to treat chronic pain. In doing so, the Manufacturer Defendants falsely minimized the risks of opioids, overstated their benefits, and generated far more opioid prescriptions than there should have been.

3. The opioid epidemic is the direct result of the Manufacturer Defendants’ deliberately crafted, well-funded campaign of deception. For years, they misrepresented the risks posed by the opioids they manufacture and sell, misleading susceptible prescribers and vulnerable patient

populations. As families and communities suffered from the scourge of opioid abuse, the Manufacturer Defendants earned billions in profits as a direct result of the harms they inflicted.

4. The Manufacturer Defendants knew that their misrepresentations about the risks and benefits of opioids were not supported by, and sometimes were directly contrary to, the scientific evidence. Certain opioid manufacturers, including Defendant Endo Pharmaceuticals, Inc., have entered agreements prohibiting them from making misrepresentations identified in this Complaint. Nonetheless, the Manufacturer Defendants continue to misrepresent the risks and benefits of long-term opioid use in WEST VIRGINIA, and they have not corrected their past misrepresentations.

5. The Manufacturer Defendants' false and misleading statements deceived doctors and patients about the risks and benefits of opioids and convinced them that opioids were not only appropriate, but *necessary* to treat chronic pain. The Manufacturer Defendants targeted susceptible prescribers, like family doctors, and vulnerable patient populations, like the elderly and veterans. And they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, medical education programs, medical conferences and seminars, and scientific articles. As a result, they successfully transformed the way doctors treat chronic pain, opening the floodgates of opioid prescriptions and dependence. Opioids are now the most prescribed class of drugs, generating billions of dollars in revenue for the Manufacturer Defendants every year.

6. In addition, the Distributor Defendants could and should have prevented the brunt of the opioid epidemic, but instead allowed the country to be flooded with prescription opioids. Under federal law, distributors are required to secure and monitor drugs as they travel through commerce, to protect them from theft, and to reject and report suspicious or unusual orders by downstream pharmacies, doctors, or patients. But the Distributor Defendants neglected this duty, turning a blind eye to known or knowable problems in their own supply chains. By doing so, the

Distributor Defendants created conditions in which vast amounts of opioids flowed freely from the Manufacturer Defendants to abusers and drug dealers—with the Distributor Defendants readily fulfilling suspicious orders from pharmacies and ignoring red flags that would require further investigation and resolution.

7. This behavior by the Distributor Defendants has allowed massive amounts of opioids to be diverted from legitimate channels of distribution into the illicit black market, fueling the opioid epidemic. The Distributor Defendants created an environment in which drug diversion can flourish. For years, the Distributor Defendants have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion but opted to pursue corporate revenues instead. All of the Defendants in this action share responsibility for creating, sustaining, and prolonging the opioid epidemic.

8. The explosion in opioid prescriptions and use has created a public health crisis in WEST VIRGINIA. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids, while their widespread use has created a population of addicted and dependent patients. When those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin. In addition to the societal impact of deaths, overdoses, and rampant addiction, Defendants' conduct has created higher demand and thus higher prices for opioids, as well as the need for expensive medical treatment for a number of covered health conditions, resulting in increased insurance costs for WEST VIRGINIA consumers.

9. Defendants' conduct has fueled skyrocketing opioid addiction and opioid-related deaths and emergency treatments, and has generated huge sales of opioids at inflated prices.

10. The direct and proximate consequence of Defendants' misconduct is that every WEST VIRGINIA purchaser of private health insurance paid higher premiums, co-payments, and

deductibles. Insurance companies have considerable market power and pass onto their insureds the expected cost of future care—including opioid-related coverage. Accordingly, insurance companies factored in the unwarranted and exorbitant healthcare costs of opioid-related coverage caused by Defendants and charged that back to insureds in the form of higher premiums, deductibles, and co-payments.

11. This action seeks to hold Defendants accountable for the economic harm they have imposed on WEST VIRGINIA purchasers of private health insurance.

PARTIES

A. Plaintiff

12. Plaintiff DEBRA HATFIELD is a natural person and resident and citizen of the State of WEST VIRGINIA. BRIAN GRAVELY was a natural person and resident of the state of WEST VIRGINIA prior to their death.

B. Defendants

Distributor Defendants

13. McKesson Corporation (“**McKesson**”) has its principal place of business in San Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the State of WEST VIRGINIA.

14. Cardinal Health, Inc. (“**Cardinal**”) has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the State of WEST VIRGINIA.

15. AmerisourceBergen Corporation has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, **AmerisourceBergen** has

distributed substantial amounts of prescription opioids to providers and retailers in the State of WEST VIRGINIA.

16. Defendant CVS Health Corporation (“**CVS**”) is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores in numerous States, including in WEST VIRGINIA, that sell prescription medicines, including opioids. At all times relevant to this Amended Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

17. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc. is a Maryland corporation with its principal offices located in Lutherville Timonium, Maryland. Defendant Rite Aid Corp. is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania. Together, Rite Aid of Maryland, Inc. and Rite Aid Corp. are referred to as “**Rite Aid.**”

18. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in WEST VIRGINIA, that sell prescription medicines, including opioids. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

19. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois. Defendant Walgreen Eastern Co. is a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids. Defendant Walgreen, Co. is a subsidiary of Walgreens Boots Alliance that operates retail drug stores. Together, Walgreens Boots Alliance, Inc., Walgreen Eastern Co. and Walgreen Co. are referred

to as “**Walgreens.**”

20. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to the hospitals, clinics, and other healthcare facilities serving the state of WEST VIRGINIA.

21. Defendant Wal-Mart Inc. f/k/a Walmart Stores, Inc. (“**Wal-Mart**”), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Amended Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

22. Defendant MIAMI-LUKEN, INC. (“**Miami-Luken**”) is an Ohio corporation with its principal place of business located in Springboro, Ohio. During all relevant times, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in WEST VIRGINIA.

23. Defendant COSTCO WHOLESALE CORPORATION (“**Costco**”) is a Washington corporation with its principal place of business in Issaquah, Washington. During all relevant times, Costco has sold and continues to sell, in WEST VIRGINIA and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

24. Defendant The Kroger Co. (“**Kroger**”) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in WEST VIRGINIA.

25. Defendants H. D. Smith, LLC d/b/a HD Smith f/k/a H. D. Smith Wholesale Drug Co., H. D. Smith Holdings, LLC, H. D. Smith Holding Company (“**H. D. Smith**”) is a Delaware

corporation with its principal place of business in Springfield, Illinois. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H. D. Smith distributed prescription opioids throughout the United States, including WEST VIRGINIA.

26. Defendant Anda, Inc. (“**Anda**”), is a Florida corporation with its principal office located in Olive Branch, Mississippi. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States, which includes WEST VIRGINIA State. In October 2016, Defendant Teva USA acquired Anda for \$500 million in cash. At all relevant times, Anda distributed prescription opioids throughout the United States, including in WEST VIRGINIA.

27. McKesson, Cardinal, AmerisourceBergen, CVS, Rite Aid, Walgreens, Wal-Mart, Miami-Luken, Costoco, Kroger, H.D. Smith, and Anda are collectively referred to hereinafter as “**Distributor Defendants.**”

Pharmaceutical Marketing and Manufacturing Defendants

28. Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and WEST VIRGINIA. Actiq and Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

29. Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a wholly- owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of

business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

30. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in WEST VIRGINIA, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in WEST VIRGINIA, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own. Through interrelated operations like these, Teva Ltd. operates in WEST VIRGINIA and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in WEST VIRGINIA itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as “**Cephalon.**”)

31. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals Inc.,

now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as "**Janssen.**") Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and WEST VIRGINIA, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "**Endo.**") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and WEST VIRGINIA. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and WEST VIRGINIA, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

33. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson

Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in WEST VIRGINIA. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as “**Actavis**.”) Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in WEST VIRGINIA. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

34. Defendant DEPOMED, INC. (“**Depomed**”) is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescription drugs in WEST VIRGINIA and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for \$1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

35. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant Mallinckrodt plc is an Irish public limited company with its

headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals (“MPMO”), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, “**Mallinckrodt**”) manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

36. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as “**Par Pharmaceutical**”). Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. (“EHS”) and Endo Pharmaceuticals, Inc. (“EPI”). EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, “Endo”), manufacture opioids sold throughout the United States including in WEST VIRGINIA.

37. Defendant Noramco, Inc. (“**Noramco**”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

38. Defendant Invidior, Inc. (“**Invidior**”) is a Delaware domestic corporation with its principal place of business in Richmond, Virginia. Indivor manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivor, Inc. is a subsidiary of Indivor, PLC, based in the United Kingdom. Indivor, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Indivor, Inc. has manufactured and/or labeled Buprenorphine shipped to WEST VIRGINIA.

39. Cephalon, Janssen, Endo, Actavis, Depomed, Mallinckrodt, Par Pharmaceutical, Noramco, and Invidior are collectively referred to hereinafter as the “**Pharmaceutical Defendants**” or “**Marketing and Manufacturing Defendants.**”

JURISDICTION AND VENUE

40. Jurisdiction of this Court arises under the laws of the United States 28 U.S.C. § 1332(a), as the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of attorney’s fees and costs.

41. Jurisdiction of this Court also arises under 28 U.S.C. § 1331 federal question jurisdiction pursuant to issues related to the Controlled Substances Act.

42. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of Ohio, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within Ohio by virtue of their distribution, dispensing, and sales of prescription opioids.

43. Venue is proper in this Court pursuant to this Court’s Case Management Order One (Doc. 232) allowing direct filing into these MDL proceedings. Plaintiff reserves the right to move for transfer at the conclusion of pretrial proceedings.

44. Per Case Management Order One, Plaintiff does not concede that Ohio law applies by directly filing in this MDL proceeding.

BACKGROUND FACTS

45. Opioid means “opium – like” and the term includes all drugs derived in whole or in part from the opium poppy.

46. The United States Food and Drug Administration’s website describes this class of drugs as follows: “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death.”

47. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called “opiates”), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

48. Before the epidemic of Defendants’ prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients’ ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

49. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the “new” market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in WEST VIRGINIA.

50. The Pharmaceutical Defendants spread their false and negligent statements by marketing their branded opioids directly to doctors and patients in WEST VIRGINIA. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of WEST VIRGINIA.

51. The Pharmaceutical Defendants' direct and branded ads negligently portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. While Endo agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in WEST VIRGINIA.

52. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through “detailers” – sophisticated and specially trained sales representatives who visited individual

doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost \$200 million on detailing branded opioids to doctors.

53. The FDA has cited at least one of these Defendants for negligent promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated “Dear Doctor” letter required Actavis to inform doctors that “Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian],” including the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.”

54. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers’ bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants’ prior misrepresentations about the risks and benefits of opioids.

55. The Pharmaceutical Defendants’ detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

56. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including WEST VIRGINIA. This unified approach ensures that Defendants’ messages were and are consistent and effective across all their marketing efforts.

57. The Pharmaceutical Defendants negligently marketed opioids in WEST VIRGINIA through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

58. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source.

59. The Pharmaceutical Defendants' negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

60. The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

61. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

62. The Pharmaceutical Defendants collaborated, through the aforementioned

organizations and groups, to spread negligent messages about the risks and benefits of long-term opioid therapy.

63. To convince doctors and patients in WEST VIRGINIA that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by conveying negligent misrepresentations to those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

64. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants negligently trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low- risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations; they continue to make them today.

65. The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a

patient education brochure that negligently claimed opioid addiction is “less likely if you have never had an addiction problem;” (b) Cephalon cosponsored APF’s Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that “[p]eople who take opioids as prescribed usually do not become addicted;” (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: “most people do not develop an addiction problem;” (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as “myth” the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are “overestimated.”

66. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

67. The FDA further exposed the falsity of the Pharmaceutical Defendants’ claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like

non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

68. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its www.opana.com website that “most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This agreement, however, did not extend to WEST VIRGINIA.

69. The Pharmaceutical Defendants negligently instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudo-addiction” – a term used by Dr. Russell Portenoy, a KOL for Cephalon, Endo, and Janssen. Defendants negligently claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these negligent claims are: (a) Cephalon cosponsored Responsible Opioid Prescribing, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let’s Talk Pain website, which in 2009 stated: “pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated;” (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudo-addiction by teaching that a patient’s aberrant behavior was the result of untreated pain.

70. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that “patients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer- term use,” and that physicians should reassess “pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

71. The Pharmaceutical Defendants negligently instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants’ misrepresentations were intended to make doctors more comfortable in prescribing opioids. A prominent example of these negligent claims is an Endo supplement in the Journal of Family Practice emphasized the effectiveness of screening tools to avoid addictions.

72. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” The Guideline emphasizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

73. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants negligently claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no

problems in stopping opioids after long-term use.

74. A CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days.

75. Pharmaceutical Defendants negligently minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient's response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

76. The Pharmaceutical Defendants negligently claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and

lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated - “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction;” (b) Cephalon cosponsored APF’s Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with “no ceiling dose” for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until “you are on the right dose of medication for your pain;” (d) an Endo pamphlet Understanding Your Pain: Taking Oral Opioid Analgesics, stated “The dose can be increased. . . . You won’t ‘run out’ of pain relief;” (e) a Janssen patient education guide Finding Relief: Pain Management for Older Adults listed dosage limitations as “disadvantages” of other pain medicines yet omitted any discussion of risks of increased opioid dosages.

77. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC states that “there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increasing dosages” above 90 morphine milligram equivalents per day.

78. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

79. Pharmaceutical Defendants’ marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

80. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s advertisements for the 2012 reformulation of Opana ER negligently claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo’s design “would provide a reduction in oral, intranasal or intravenous abuse.” Moreover, Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

81. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was “designed to be, or is crush resistant.” New York found those statements false and negligent because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies – even when they work – “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.”

82. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.” In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes

examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants negligently and misleadingly touted the benefits of long-term opioid use and negligently and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and negligent claims, they continue to make them today.

83. For example, the Pharmaceutical Defendants negligently claimed that long-term opioid use improved patients’ function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as “a fact” that “opioids may make it easier for people to live normally” such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Responsible Opioid Prescribing, by Cephalon and Endo, taught that relief of pain by opioids, by itself, improved patients’ function; (f) Cephalon cosponsored APF’s Treatment Options: A Guide for People Living with Pain counseling patients that opioids “give [pain patients] a quality of life we deserve;” (g) Endo’s NIPC website painknowledge.com claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse;” (h) Endo CMEs titled Persistent Pain in the Older Patient claimed that chronic opioid therapy had been “shown to reduce pain and improve depressive

symptoms and cognitive functioning;” (i) Janssen sponsored, funded, and edited a website, Let’s Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.”

84. These claims find no support in the scientific literature. The 2016 CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is *unlikely*” (emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

- “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”
- “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

85. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

86. The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.” In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that]

patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

87. The Pharmaceutical Defendants also negligently and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

88. Cephalon negligently marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

89. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs,

KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

90. Cephalon’s negligent marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

91. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

92. As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in WEST

VIRGINIA. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

93. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo has recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

94. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for

chronic pain.

95. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and “educational” materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Other Pharmaceutical Defendants, such as Janssen, ran similar websites that masked their own direct role.

96. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants’ negligent messages was not apparent to medical professionals who relied upon them in making treatment decisions.

97. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, municipalities, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Plaintiff now assert. Plaintiff did not know of the existence or scope of Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

98. The Pharmaceutical Defendants’ misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids

were potentially addictive.

99. The Pharmaceutical Defendants' negligent marketing scheme caused and continues to cause doctors in WEST VIRGINIA to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' negligent marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' negligent marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' negligent marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

100. The Pharmaceutical Defendants' negligent marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their negligent marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

101. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' negligent marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and WEST VIRGINIA. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to negligent marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

102. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has

quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

103. Contrary to the Pharmaceutical Defendants’ misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors’ prescribing habits have played in the opioid epidemic.

Depomed

104. Depomed sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians. Depomed has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER.

105. Depomed sales representatives promoted Lazanda for unsafe and unapproved uses.

106. Lazanda is only indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” Despite the drug’s explicit limitation, Depomed actively promoted Lazanda to physicians who do not treat cancer patients. Not only did Depomed instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Company also discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors’ business.

107. When it launched Lazanda in 2011, the Company's management, from the start, disregarded the FDA's limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of ROOs and Lazanda-like drugs.

108. Sales representatives were pressured to target pain management physicians. Area managers at Depomed regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

109. Depomed also strongly discouraged sales representatives from targeting physicians treating cancer patients. Sales representatives had to "make a case" for using any portion of their allotted marketing money to call on cancer treating physicians. And employees who did call on cancer treating physicians were disciplined.

110. One Depomed sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writerDepomed explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company's then head of sales for the United States.

111. Depomed sales representatives were also trained to deal with (rightful) pushback from physicians. For example, when confronted with the common statement from a physician that "it's extremely rare that we see cancer patients," Depomed trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives

were trained to respond by saying “well tell me about your patients taking Actiq,” and then extol the relative benefits of switching those patients to Lazanda.

112. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017.

113. Depomed sales representatives promoted Nucynta and Nucynta ER for unsafe and unapproved uses.

114. On April 2, 2015, Depomed acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for \$1.05 billion in cash. The Nucynta franchise is an opioid that includes Nucynta ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

115. Nucynta’s annual sales increased in the U.S. from \$189.9 million in 2015 to approximately \$281.3 million in 2016, quickly becoming Depomed’s best-selling product. This marked a 48% year-over-year growth in sales of Nucynta in just one year.

116. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed’s illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, Depomed promoted the use of opioids for all manner of pain management while downplaying the drug’s addictive nature, often promoting the drug as a safer alternative to opioids, despite this not being on the FDA label.

117. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids.

In February 2017, Depomed's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

118. The FDA-approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as “a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.” Nowhere on the FDA-approved label does it say or mention that Nucynta is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its manufacturer (formerly Janssen) claiming these benefits in its sales pitches and marketing.

119. Nonetheless, Depomed directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

120. Depomed management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way. 245. On June 23, 2015 investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that “[a]lthough not in the label, there's a very low abuse profile and side effect rate.”

121. Additionally, in a March 14, 2015 presentation at the ROTH Conference, then Depomed CEO Schoeneck stated: “The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label.” In February 2017, Schoeneck also told investors that Depomed was “initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace.” The purpose of this was to “be able to get it hopefully into the label.”

122. Depomed's marketing push was “Think Differently.” Sales representatives were told

that Nucynta is a “safer opioid.” They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

123. Depomed actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

124. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against Opioids. Former President and CEO James Schoeneck described to investors that Nucynta had “different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about” and that “there’ll be relatively little impact on [Depomed] compared to where some other companies may fall in at.”

125. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

126. Due to the worsening headwinds within the Opioid market, Depomed ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017.

Mallinckrodt

127. In WEST VIRGINIA and nationwide, Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids.

128. Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion.

129. Upon information and belief, Mallinckrodt promoted the use of opioids for chronic pain through “detailers,” who were sales representatives who visited individual physicians and their staff in their offices and small group speaker programs. Mallinckrodt sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians.

130. Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain- Topics.org, a now-defunct website that touted itself as “a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.”

131. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb (“Gottlieb”), the new commissioner of the FDA, \$22,500 for a speech in London, shortly after the U.S. presidential election. Gottlieb has also received money from the HDA, an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.

132. Mallinckrodt, combined with five other opioids manufacturers, made payments exceeding \$140,000 to ten members of the ACPA Advisory Board.

133. Mallinckrodt’s aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction.

134. Mallinckrodt, plc, Mallinckrodt, LLC and SpecGx, LLC and their subsidiaries are

“Pharmaceutical Defendants” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Pharmaceutical Defendants in the existing complaint.

Par Pharmaceutical

135. Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. (“EHS”) and Endo Pharmaceuticals, Inc. (“EPI”). EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, “Endo”), manufacture opioids sold throughout the United States. Plaintiff adopts all allegations and causes of action alleged against Endo and the Pharmaceutical Defendants alleged in the existing complaint against Par Pharmaceutical.

Noramco

136. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital. All allegations pertaining to Janssen also apply to Noramco. Plaintiff adopts all allegations and causes of action alleged against the Pharmaceutical Defendants alleged in the existing complaint against Noramco.

Invidior

137. Invidior manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivor, Inc. has manufactured and/or labeled Buprenorphine shipped to WEST VIRGINIA. Plaintiff adopts all allegations and causes of action alleged against the Pharmaceutical Defendants alleged in the existing complaint against Invidior.

DISTRIBUTOR DEFENDANTS’ WRONGFUL CONDUCT

138. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants

Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90 % of all revenues from drug distribution in the United States, an estimated \$378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

139. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid “diversion” occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

140. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

141. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

142. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

143. Every year, thousands of people in WEST VIRGINIA misuse and abuse opioid pain relievers that can lead to addiction, neonatal abstinence syndrome, overdose and death.

144. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged

as a public health crisis in the United States.

145. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin.

146. Plaintiff has been significantly damaged by the effects of the Distributor Defendants' opioid diversion.

147. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

148. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

149. By violating the CSA, the Distributor Defendants are also liable under the law of WEST VIRGINIA as herein alleged.

150. The CSA creates a legal framework for the distribution and dispensing of controlled

substances. Congress passed the CSA partly out of a concern about “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

151. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a “registration” with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

152. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

153. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA’s Automation of Reports and Consolidation Orders System (“ARCOS”) is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors’ controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable

controlled substances must report acquisition and distribution transactions to the DEA.

154. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

155. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

156. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

157. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, and have committed repeated violations of the laws and regulations of the United States as cited above consequently making them liable under WEST VIRGINIA law.

158. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications,

documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the “red flags” distributors should look for to identify potential diversion.

159. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

160. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

161. The September 27, 2006 letter reminded registrants that they were required by law to

exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

162. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

163. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

164. These industry guidelines stated: “At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

165. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

166. For example, a Cardinal executive claimed that Cardinal uses “advanced analytics” to monitor its supply chain. He further extolled that Cardinal was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity” (emphasis added).

167. McKesson has publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our Country.”

168. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

169. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

170. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the Controlled Substances Act.

171. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

172. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

173. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection

with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

174. Relying upon state laws and regulation, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

175. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

176. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff.

177. The Distributor Defendants have supplied massive quantities of prescription opioids in WEST VIRGINIA with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

178. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into WEST VIRGINIA was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

179. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight,

security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in WEST VIRGINIA; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

180. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing patients and citizens of WEST VIRGINIA to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

181. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the patients and citizens of WEST VIRGINIA, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

182. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of WEST VIRGINIA with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

183. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, neo-natal addiction, and NAS.

184. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn,

perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

185. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to patients and citizens of WEST VIRGINIA were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, Plaintiff.

186. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become patients in WEST VIRGINIA, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency- that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

187. If any of the Distributor Defendants adhered to effective controls to guard against diversion, the Plaintiff would have avoided significant damages.

188. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting WEST VIRGINIA. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff. The Distributor Defendants knew full well that Plaintiff would be unjustly forced to bear these injuries and damages.

189. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff. Their conduct poses a continuing economic threat to the communities that must deal with ongoing needs of children afflicted with NAS.

CVS

190. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores, including in WEST VIRGINIA, that sell prescription medicines, including opioids.

191. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

192. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations.

193. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

194. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney’s Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

195. This fine was preceded by numerous others throughout the country.

196. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

197. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

198. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state’s prescription monitoring program website and review a patient’s prescription history before dispensing certain opioid drugs.

199. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

200. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

201. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

202. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

203. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

204. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

205. CVS has had knowledge and/or notice of the opioid problem since at least 2002.

206. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

207. In their capacity as wholesale distributors, CVS and its subsidiaries are “Distributor Defendants” as used in the existing complaint. Plaintiff adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against CVS.

Rite Aid

208. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in WEST VIRGINIA, that sell prescription medicines, including opioids.

209. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

210. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the third-largest drug store chain in the United States, with annual revenue of more than \$21 billion.

211. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.

212. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R.1301.76(b).

213. In their capacity as wholesale distributors, Rite-Aid and its subsidiaries are “Distributor

Defendants” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Rite Aid.

Walgreens

214. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in WEST VIRGINIA.

215. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

216. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black market sales.

217. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

218. Walgreens’ WEST VIRGINIA operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens’ WEST VIRGINIA pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

219. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone

in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the CSA or the health of communities.

220. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in WEST VIRGINIA. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ WEST VIRGINIA pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its WEST VIRGINIA stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

221. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).

222. The Massachusetts Attorney General’s Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

223. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and didn’t use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

224. In their capacity as wholesale distributors, Walgreens and its subsidiaries are “Distributor Defendants” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Walgreens.

Wal-Mart

225. Walmart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States.

226. In its capacity as a wholesale distributor, Wal-Mart is a “Distributor Defendant” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Wal-Mart.

Miami-Luken

227. During all relevant times, upon information and belief, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in WEST VIRGINIA.

228. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken’s Certificate of DEA Registration.

229. In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped controlled substances, particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern WEST VIRGINIA, and southern West Virginia.

230. In early 2016, Miami-Luken agreed to pay the state of West Virginia \$2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.

231. In its capacity as a wholesale distributor, Miami-Luken is a “Distributor Defendant”

as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Miami-Luken.

CostCo

232. Costco failed to track and report suspicious sales of its opioid drugs.

233. Costco is a “registrant” under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

234. Contrary to its duties as a registrant, in 2017, Costco Wholesale was fined \$11.75 million as a result of a multijurisdictional investigation by the DOJ relating to CSA violations.

235. According to the investigation, Costco pharmacies filled prescriptions that were incomplete, lacked valid DEA registration numbers or were for substances beyond various doctors’ scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies.

236. Between January 1, 2012 and December 31, 2015, certain Costco pharmacies dispensed controlled substances inconsistent with their compliance obligations under the CSA and its implementing regulations. The violations include: filling prescriptions from practitioners who did not have a valid DEA number, incorrectly recording the practitioner’s DEA number, filling prescriptions outside the scope of a practitioner’s DEA registration, filling Prescriptions that did not contain all the required information, failing to maintain accurate dispensing records, and failing to maintain records for their central fill locations in Sacramento, California and Everett, Washington.

237. According to U.S. Attorney Eileen M. Decker: “These are not just administrative or paperwork violations – Costco’s failure to have proper controls in place in its pharmacies played a role in prescription drugs reaching the black market....”

238. Furthermore, Costco could and should have taken action that: (a) limited to 7 days the

supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

239. Having knowledge and/or notice of the damages that Costco's conduct had caused to Plaintiff, Costco failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Costco, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Costco ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

240. Costco could have and should have implemented these measures at any point in the last 15 years.

241. And the failure to take such steps that Costco should have taken was negligent and did result in significant damages to Plaintiff.

242. In its capacity as a wholesale distributor, Costco is a "Distributor Defendant" as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Costco.

H.D. Smith

243. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H. D. Smith distributed prescription opioids throughout the United States.

244. H. D. Smith has also routinely been found to have violated its duties to report suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H. D. Smith provided two pharmacies in Williamson, WV, a town with a population of 3,191, combined total of nearly 5 million hydrocodone and oxycodone pills - approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, WV.¹⁸⁸ According to press reports, H. D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012.¹⁸⁹ Press accounts further indicate that H. D. Smith did not submit any suspicious order reports to the state for at least a decade.¹⁹⁰ Upon information and belief, H. D. Smith engaged in similar wrongful activities in WEST VIRGINIA.

245. In its capacity as a wholesale distributor, H.D. Smith is a “Distributor Defendant” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against H.D. Smith.

Anda

246. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) acquired Anda for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in WEST VIRGINIA.

247. In its capacity as a wholesale distributor, Anda is a “Distributor Defendant” as used in the existing complaint. Plaintiff adopts all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Anda.

Discovery Rule and Tolling

248. The Defendants’ unfair and deceptive conduct was well concealed, and only recently uncovered through exhaustive investigation and research. The defendants deliberately conducted much of their deception through in-person sales visits, in order to avoid generating a potentially discoverable paper trail of their misconduct.

249. Discovering the nature and extent of the defendants’ unfair and deceptive conduct has been a time-consuming and complex process, further strained by defendants’ lack of cooperation and baseless denials. Due to Defendants’ deception, any statutes of limitation otherwise applicable to any claims asserted herein against all defendants have been tolled by the discovery rule and rules regarding fraudulent concealment.

CAUSES OF ACTION

COUNT I – NUISANCE

250. Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

251. The nuisance is the over-saturation of opioids in WEST VIRGINIA for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use, including the increasing incidence of NAS.

252. All Defendants substantially participated in nuisance-causing activities.

253. Defendants’ nuisance-causing activities include selling or facilitating the excessive sale of prescription opioids to the patients and citizens of WEST VIRGINIA, as well as to unintended

users, including newborns and children, pregnant women, and potential mothers.

254. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

255. Defendants' activities unreasonably interfere with the rights of Plaintiff.

256. The Defendants' interference with the rights of Plaintiff is unreasonable because it:

- a. Has harmed and will continue to harm the children and public health services of WEST VIRGINIA;
- b. Is proscribed by statutes and regulation, including the CSA and the consumer protection statute;
- c. Is of a continuing nature and it has produced long-lasting effects; and
- d. Defendants have reason to know their conduct has a significant effect upon Plaintiff.

257. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities.

258. The resources of the community of the Plaintiff is insufficient to deal with needs created by the Opioid Crisis, and these limited resources are being unreasonably consumed in efforts to address the Crisis, including efforts to address the overwhelming number of children born with NAS.

259. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants dissemination of

false “scientific” facts and advice.

260. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale. Pharmaceutical Defendants flooded the distribution channels and the geographic and demographic area of WEST VIRGINIA with opioid pills. Distributor Defendants had the power to shut off the supply of illicit opioids to patients and consumers of WEST VIRGINIA, yet they did the opposite by flooding the U.S. (including WEST VIRGINIA) with opioid pills.

261. As a direct and proximate result of the nuisance, the community of Plaintiff has born a great burden trying to remedy the harms caused by Defendants’ nuisance-causing activity, including, but not limited to, costs of hospital services, counseling, healthcare, and child services.

262. The deceased BRIAN GRAVELY also has suffered unique harms different from the public at large, namely, that they personally suffered from addiction, it’s harmful effects, and they died.

263. The effects of the nuisance can be abated, and the further occurrence of such harm can be prevented. All Defendants share in the responsibility for doing so.

264. Defendants should be required to pay the expenses Plaintiff and their community have incurred or will incur in the future to fully abate the nuisance.

COUNT II - NEGLIGENCE AND GROSS NEGLIGENCE

265. Plaintiff reasserts the allegations of the foregoing paragraphs as if set forth fully herein.

266. Defendants owe a non-delegable duty to Plaintiff DEBRA HATFIELD and to the deceased DEF to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

267. There is no social value to Defendants’ challenged behavior. In fact, Defendants’ entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

268. On the other hand, there is immense social value to the interests threatened by

Defendants' behavior, namely the health, safety, and welfare of Plaintiff.

269. Defendants' behavior caused a substantial injury and damage to Plaintiff.

270. Defendants' conduct fell below the reasonable standard of care and was negligent.

Their negligent acts include:

- a. Consciously supplying the market in WEST VIRGINIA with highly-addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;
- b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential patient;
- c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- d. Failing to properly train or investigate their employees;
- e. Failing to properly review and analyze prescription orders and data for red flags;
- f. Failing to report suspicious orders or refuse to fill them;
- g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;
- h. Failing to police the integrity of their supply chains; and
- i. Creating misleading information with the intention of having prescribing physicians rely upon it.

271. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

272. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

273. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

274. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

275. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, *e.g.*, the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

276. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis Plaintiff. Defendants owe a special duty to Plaintiff. That duty cannot be delegated to another party.

277. Plaintiff is without fault, and the injuries to Plaintiff would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

278. The aforementioned conduct of Defendants proximately caused damage to Plaintiff.

COUNT III - CIVIL CONSPIRACY

279. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out herein.

280. The Pharmaceutical Defendants continuously supplied prescription opioids to the

Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their common law duties and violating the CSA. The Distributor Defendants continuously supplied prescription opioids to pharmacies despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties and violating the CSA.

281. Without the Distributor Defendants' supply of prescription opioids, pharmacies would not be able to fill and dispense the increasing number of prescription opioids throughout WEST VIRGINIA.

282. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

283. The Pharmaceutical Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Pharmaceutical Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Pharmaceutical Defendants ignored the warning signs of opioid diversion.

284. As a result of the concerted actions between and among the Defendants, the Plaintiff has suffered damages.

285. Plaintiff demands judgment against each Defendant for compensatory damages.

COUNT IV - PRODUCTS LIABILITY

286. Plaintiff reasserts the allegations in the foregoing paragraphs as if fully set out herein.

287. At all times material to this action, Defendants were engaged in the business of the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of opioid products.

288. At all times material to this action, Defendants' opioid products were expected to

reach, and did reach, consumers in the State of WEST VIRGINIA and throughout the United States, including Plaintiff herein, without substantial change in the condition in which they were sold.

289. Defendants knew that the damage causing characteristics of Defendants' product include its addictive properties and its damaging impact on those who use its product.

290. Defendants knew that prolonged use of opioids leads to decreased effectiveness, requiring increases in doses to achieve the same level of pain relief, markedly increasing the risk of significant side effects and addiction. Defendants conducted studies documenting these risks, yet failed to publish the results or warn of the documented risks.

291. The risks of opioid addiction are grave and Defendants had a duty to warn about these risks.

292. Providing such warnings would have been easily feasible, but would have interfered with Defendants' marketing efforts. Instead, Defendants' engaged in a multimillion dollar marketing and advertising effort promoting falsehoods and minimizing the risk of addiction and withdrawal from long term opioid use.

293. Defendants knew that opioids are too addictive and too debilitating for long-term use for chronic pain, barring exceptional circumstances. Defendants knew that the only safe uses for their product were end of life care, short term pain relief after surgery, and pain relief related to cancer. Defendants failed to warn WEST VIRGINIA physicians, and other individuals of the dangers of using their product outside of these areas.

294. Defendants' products were unreasonably dangerous at the time they left the control of Defendants because of inadequate warning.

295. Because of Defendants' knowledge of the risks to those who take their product, and their extensive efforts to obscure these risks, Defendants are liable for all resulting damages caused to Plaintiff.

296. The opioid product manufactured and/or supplied by Defendants were defective in design in that an alternative design exists that would prevent addiction and severe and permanent injury to those who take their product.

297. A reasonably prudent manufacturer or seller would not have put Defendants' products on the market had it known of the products' dangerous condition and/or defective design.

298. Defendants designed their product in such a way that it could easily be abused by crushing of pills with the resulting powder ingested by inhalation or injection.

299. Defendants were aware that their products were being abused in this manner on a large scale, making this a reasonably anticipated use.

300. Despite this knowledge, Defendants only recently altered the design of their product to be "enteric," that is, changed it to a form that prevented such crushing and consumption. This change was only made after years of public and legal pressure.

301. Further, Defendants promoted their unreasonably dangerous design by actively undercutting the prescription of alternative nonsteroidal anti-inflammatory drugs, pushing the misinformation that such non-opioid drugs were not effective for the treatment of long term pain.

302. Therefore, Defendants are liable for the damages caused to the Plaintiff by their opioid products' unreasonably dangerous and defective design and inadequate warnings of their opioids' addictive properties.

COUNT V - PUNITIVE DAMAGES

303. Plaintiff reasserts each and every allegation set forth in all preceding paragraphs as if fully restated herein.

304. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiff. Plaintiff is thus entitled to recover punitive damages against Defendants.

305. Defendants were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiff, in their activities and in failing to warn Plaintiff of dangers well known to Defendants, which acts exhibited a deliberate disregard for the rights and safety of Plaintiff.

306. Defendants realized the imminence of danger to Plaintiff and other members of the public, but continued with deliberate disregard and complete indifference and lack of concern for the probable consequences of their acts.

307. As a direct result of Defendants' deliberate disregard for the rights and safety of others, gross negligence, malicious, oppressive, willful, wanton, reckless, and/or criminal indifference to civil obligations affecting the rights of others, including Plaintiff, Plaintiff suffered the injuries and dangers stated above.

308. Defendants' acts as described herein exhibited deliberate disregard for the rights and safety of others and were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiff. An award of punitive and exemplary damages is therefore necessary to punish Defendants, and each of them, and to deter any reoccurrence of this intolerable conduct. Consequently, Plaintiff is entitled to an award of punitive damages.

309. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiff. Plaintiff is thus entitled to recover punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter Defendants and others from similar wrongful conduct in the future.

COUNT VI – UNJUST ENRICHMENT

310. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the

paragraphs above as if fully set forth herein.

311. To the detriment of Plaintiff, all Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

312. All Defendants have voluntarily accepted and retained the inflated prices paid for their opioid products with full knowledge that they were not lawfully entitled to it.

313. Plaintiff bears the costs of the benefits conveyed to all Defendants in the form of increased insurance premiums.

314. Between Defendants and Plaintiff, it would be unjust for Defendants to retain the benefits attained by their wrongful actions.

315. All Defendants have been unjustly enriched, in the form of inflated prices, at the expense of Plaintiff who is entitled in equity to disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount deemed appropriate by the Court, and any other relief the Court deems just and proper to remedy Defendants' unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff DEBRA HATFIELD requests that the Court grant the following relief:

- a. Injunctive Relief, including enjoining the Defendants and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law as described herein, and by temporary, preliminary or permanent injunction force the Defendants and all other persons acting in concert or participation with them to abide by the Controlled Substances Act, provide the required control measures, and prevent unauthorized users from obtaining opioids;
- b. Compensatory damages;

- c. Restitution;
- d. Punitive damages;
- e. Attorneys' fees and costs;
- f. Pre and Post Judgment Interest;
- g. All such other relief this Court deems just and fair; and
- h. Plaintiff seeks a trial by jury for all counts so triable.

Respectfully submitted by:

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